

Instructional Requirements for Investigators Affiliated with or Conducting Research within the Jurisdiction of Washington State Government Agencies

Why is training important and necessary?

A recent series of well-publicized lapses in human subject protection programs resulting in the deaths of several subjects and the suspension of approval to conduct research at a number of nationally recognized research institutions has raised concerns about the current system for protecting human research subjects. There is a consensus that the primary responsibility for protecting subjects lies with researchers, their institutions and institutional review boards. However, an exemplary system of protection requires more than mere compliance with existing policies and regulations. It requires conducting research “within a culture of concern and respect for research participants.”¹

Education and training in research ethics is central to fostering this culture of respect. In October, 2000, NIH began to require documentation of completion of appropriate education in the protection of human research participants for all key personnel of research involving human subjects. In December, 2000, as part of the new Federalwide Assurance (FWA) process, the federal Office for Human Research Protections (OHRP) required all institutions conducting research under an FWA to establish “continuing programs to educate IRB members, IRB staff, and research investigators about human subject protection requirements.”²

The Washington State Agency training requirements are grounded in these federal requirements and reflect our belief that appropriate education and training is an important component of an effective system of human subject protections.

Who is required to take the training?

Principal Investigators of all research projects conducted in the jurisdiction of these Washington State Agencies (Department of Social and Health Services, Department of Health, and Department of Labor and Industries) are required to complete the training. All research staff responsible for the design of the study and all those in contact with human subjects and/or identifiable data (e.g., interviewers and data analysts), are strongly encouraged to take the training. Staff and members of the Washington State Institutional Review Board (WSIRB), the designated Institutional Review Board for these Washington State Agencies, are required to take the training.

¹ “Ethical and Policy Issues in Research Involving Human Participants, SUMMARY,” National Bioethics Advisory Commission, Bethesda, Maryland, August, 2001.

² See the FWAs for DSHS, DOH and L&I at (LINK).

When must the training be completed?

Effective July 1, 2002, all Principal Investigators submitting new research proposals to the WSIRB must complete training before their research will be approved. Principal Investigators of ongoing research projects must complete training before continuation approval for their research will be extended. Staff and members of WSIRB must complete training within three months of their initial appointment to the WSIRB or their employment as staff.

What is the CITI training course?

While the training requirement can be satisfied by attending one of the in-person tutorials sponsored by the University of Washington and the Fred Hutchinson Cancer Research Center, we expect that most Washington State Agency investigators and IRB members require a more flexible method of completing this requirement. After review of a number of web-based training programs, we selected the course developed by the Collaborative IRB Training Initiative (CITI) and the University of Miami. The CITI Human Subjects Research Educational Program consists of 13 modules that focus on different aspects of research ethics and human subject protection. In addition there is a "Hot Topics" module which provides information on current issues. Each module includes a brief quiz which must be taken to complete the module.

What modules are required?

Investigators are required to take the following **Core Modules** in the CITI course:

- Module 1: HISTORY AND ETHICAL PRINCIPLES
- Module 2: IRB REGULATIONS AND REVIEW PROCESS
- Module 3: INFORMED CONSENT
- Module 4: SOCIAL AND BEHAVIORAL RESEARCH
- Module 5: RECORDS-BASED RESEARCH
- Module 7: RESEARCH WITH PROTECTED POPULATIONS
- Module 9: RESEARCH INVOLVING MINORS
- Module 11: POPULATION RISKS, GROUP HARMS & COMMUNITY CONSULTATION

Investigators conducting research involving topics addressed in any of the following **Additional Modules** are required to complete those CITI modules:

Module 6: GENETIC RESEARCH IN HUMAN POPULATIONS

Module 8: RESEARCH INVOLVING PRISONERS

Module 10: RESEARCH INVOLVING PREGNANT WOMEN, FETUSES AND NEONATES

Module 12: RESEARCH WITH INVESTIGATIONAL DRUGS, DEVICES AND BIOLOGICS

Module 13: RESEARCH IN THE DEPARTMENT OF VETERANS AFFAIRS

Module 14: HOT TOPICS (e.g., TISSUE BANKING, DSMBs)

After completing all required modules, investigators must complete the requirements posted on the Washington State Agencies Institutional Page at the CITI site.

IRB members and staff are required to complete all 14 modules and the Washington State Agencies Institutional Page.

How long will it take to complete the Training?

Each module takes from 10 to 30 minutes to complete. The Core Modules are estimated to take about 2 to 3 hours to complete. The course may be broken into several sessions each devoted to completing one or more module and the related quiz.

What is considered a passing score?

A score of 70% averaged over all the required modules is considered a passing score. If you have less than a passing score, you will be allowed to retake selected modules to improve your average score. Please contact the HRRS Training Coordinator if you need to arrange to retake any modules.

How do I document that I have completed the training?

When you complete all of the required modules you may fill out the CITI Certificate of Completion form and send it directly to the HRRS Training Coordinator. The HRRS Training Coordinator is notified weekly of the modules that individuals have completed. When all the required modules have been completed, your name will be posted on the Washington State Agency List of Training Participants (**LIST LINK**).

Who do I contact if I have questions?

Please contact Lilly Moneer, Training Coordinator, at 360 902-8075 or by email at moneelg@dshs.wa.gov.